ORAL ANSWERS TO QUESTIONS

Anti-PHD Immunoglobulin manufactured by the Bharat Serums and Vaccines

*81. SHRI ANAND SHARMA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the anti-PHD immunoglobulin manufactured by the Bharat Serums and Vaccines Limited was found to contain AIDS anti-bodies;

(b) the total number of persons injected with anti-RHD immunoglobulin in the country so far; and

(c) what steps have been taken to ensure the safety of vaccines of drugs based on human serum?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (c) A statement is laid on the Table of the Sabha.

Statement-I

(a) to (c) Two samples of injection anti-D immunoglobulin of batch No. 6/88 produced by M|s. Bharat Serums and Vaccines Pvt. Ltd. tested at All India Institute of Medical Sciences were found positive for HIV antibodies.

While it will not be possible to indicate the number of persons injected with anti-D Immunoglobulin a statement showing the number of vials of different strengths produced, distributed and subsequently withdrawn in respect of batch No. 6|88 by this firm is annexed|enclosed [*See* below]

On the 6th May, 1986, administrative instructions were issued by the Drug Controller of India to all the State Drug Controllers that the blood banks should comply with the requirement of accepting blood from professional donors only on production of a certificate regarding of HIV infection.

On receipt of information from the Medical Superintendent, All India Institute of Medical Sciences, about the presence of HTV anti-bodies in samples of anti-D immunoglobulin injection produced by M|s. Bharat Serums and Vaccines Pvt. Ltd., the Drug Controller of India instructed the Commissioner, Food Drug Administration, Maharashtra, who gave orders to recall all batches of injections anti-D Immunoglobulin and stop production and distribution of all blood products manufactured by M|s. Bharat Serums and Vaccines Pvt. Ltd.

The Drug Controller of India had a meeting with blood product manufacturers on 5-2-1989 in Bombay. All the six manufacturers in Maharashtra attended. In view of the seriousness of the matter, it was decided that all manufacturers will send samples of all products of all batches of 1988-89 for testing. Only these found to be free from HIV anti-bodies would be released. The Director General of Health Services has issued detailed instructions to all State Drug Controllers on 14-2-1989. The instructions cover the following aspects:

1. Manufacturers of blood products are required to test samples of blood from every bleeding, for HIV anti-bodies. Only those blood units which are free from HIV anti-bodies should be used for manufacture of blood products.

2. The pool of plasma before fractionation is required to be tested for HIV anti-bodies.

3. Standard manufacturing processes have been suggested for manufacture of blood products.

4. As a measure of abundant caution, blood products containing immunoglobulin preparations are required to be screened for HIV antibodies and released for marketing only if they are found free from HIV anti-bodies.

5 State Drug Control Authority should undertake random checking of immunoglobulin preparations by getting the samples tested accredited laboratories.

Statement-II

The Number of VIALS of Anti-RHD immonoglobulin (Batch No. 6/88) produced Distributed and subsequently withduced by M/s. Bharat Serum, and Vaccines Pvt. Ltd.

Strength	Production (No. of vials)	Distributed (No. of vials)	Withdrawn by the firm (No. of vials)
100 mcg	339	240	75
250 mcg	442	228	57
350 mcg	383	383	165
400 mcg	819	463	18

SHRI ANAND SHARMA: My question is ...(*Interruptions*)... no screening the blood was done ...(*interruptions*).

Have you segregated the patients. Have you identified the people injected. If so, I want to know whether the vaccine produced by the Bharat Serums and Vaccines Ltd. was subjected to Elisa test and Western blot test. If not, how was the certification allowed. (*Interruptions*)

12.00 NOON.

KUMARI SAROJ KHAPARDE: The firm have been asked to immediately stop manufacture and distribution of all such products and also to recall from the market all the anti-D immunoglobulin products manufactured by this firm. Action in the form of stoppage of production and distribution has already been taken.

MR. CHAIRMAN: Question Hour is over.

Now Papers to be laid on the Table.

WRITTEN ANSWERS TO QUESTIONS

Sale of anti-RHD vaccine containing AIDS anti-bodies at the AIIMS, Super Bazar Unit

*82. SHRI GURUDAS DAS GUPTA:
SHRI PARVATHANENI UPENDRA:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that the presence of the AIDS anti-bodies was discovered in the anti-RHD vaccine sold by the Super Bazar Unit in the All India Institute of Medical Sciences (AIIMS), New Delhi;

(b) if so, the details thereof; and

(c) what action was taken for its withdrawal from the market and also against the company which manufactured this Vaccine?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (c) Two samples of injection anti-D immunoglobulin of batch No. 6|88 produced by M|s. Bharat Serums and Vaccines Pvt. Ltd., tested at the All India Institute of Medical Sciences were found positive for HIV anti-bodies.

The Commissioner, Food and Drugs Administration, Maharashtra took steps to stop further production and distribution of all blood products by the firm and to recall from the market all the stocks of anti-D immunoglobulin injections.

The Drug Controller of Delhi took action to freeze stocks of batch No. 6|88 of anti-D immunoglobulin injections.

Particulars of the distribution of batch No. 6|88 were given to the State Drug Controllers and they were requested to take steps to freeze the stocks and also to ensure withdrawal of stocks from Government Hospitals and nursing homes.